Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults

Protocol summary

Study aim
Study and compare the effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults and taking advantage of the outcomes to improve gait and balance and decrease the risk of falling

Design
A randomized, single-blind clinical trial with a parallel group design. The subjects are randomized with Permuted Block into three groups (two interventional and one control groups).

Settings and conduct
Subjects are recruited from the older adults who refer to Jahandidegan Center in Shiraz city. the study is single-blinded and the assessor of balance and gait outcome is unaware of subjects allocation to the groups.

Participants/Inclusion and exclusion criteria
inclusion criteria: age of 65 years old or more, obtain score 24 or more out of 30 in MMSE and score lower than 7 in GDS, the ability to walk without assistive devices for at least 20 meters exclusion criteria: neurologic, orthopedic and musculoskeletal disorders that can affect gait, history of head injury, cardiovascular and respiratory disorders, chest pain with activity, cancer, history of surgery in lower limbs, spinal column or head during the past 6 months and the need to use Oxygen capsule

Intervention groups
group 1: single-task training (6 weeks of single-task balance and gait training) group 2: dual-task training (6 weeks of dual-task balance and gait training) group 3: control group (without intervention)

Main outcome variables
Fullerton Advanced Balance scale (FAB); Timed Up & Go test; Activities-specific Balance Confidence، gait performance under single- and dual-task conditions

General information

Reason for update
The actual recruitment dates were added.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180429039470N1**
Registration date: **2018-06-17, 1397/03/27**
Registration timing: **prospective**

Last update: **2020-12-13, 1399/09/23**
Update count: **2**

Registration date
2018-06-17, 1397/03/27

Registrant information

Name
Reza Salehi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 8051

Email address
salehi.re@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-12, 1397/03/22

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
2018-06-30, 1397/04/09

Actual recruitment end date
2018-07-16, 1397/04/25

Trial completion date
2018-09-23, 1397/07/01

Scientific title
Effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults

Public title
Effects of gait and balance training on gait and balance in older adults

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
age 65 years old or more obtain score 24 or more out of 30 in MMSE obtain score lower than 7 in GDS the ability to walk without assistive devices for at least 20 meters

Exclusion criteria:
neurologic disorders including Parkinson's, MS, stroke, peripheral neuropathy that can affect gait performance specific orthopedic and musculoskeletal disorders including knee replacement or fracture history of head injury cardiovascular and respiratory disorders severe chronic pain and chest pain with activity cancer history of surgery in lower limbs, spinal column or head during the past 6 months the need to use Oxygen capsule

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **69**
Actual sample size reached: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted Block Randomization Randomization was achieved with an online randomization application to provide random permuted blocks with a block size of 6.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor of balance and gait outcome was unaware of subjects allocation to the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
15794 – 61357

Approval date
2018-06-09, 1397/03/19

Ethics committee reference number
IR.AJUMS.REC.1397.212

Health conditions studied

1

Description of health condition studied
gait and balance in older adults

ICD-10 code
R26.89

ICD-10 code description
Other abnormalities of gait and mobility

Primary outcomes

1

Description
Gait performance

Timepoint
Baseline، at the end of the sixth week and 3 months after the trial

Method of measurement
Gait harmonic ratio

Secondary outcomes

1

Description
balance performance

Timepoint
Baseline, at the end of the sixth week and 3 months after the trial

Method of measurement
Fullerton advanced balance scale (FAB)

2

Description
Functional activity

Timepoint
baseline, at the end of the sixth week and 3 months after the trial

Method of measurement
Timed Up & Go test

3

Description
Balance confidence
Timepoint
Baseline, at the end of the sixth week and 3 months after the trial
Method of measurement
Activities-specific Balance Confidence scale

Intervention groups

1

Description
Intervention group 1: single-task gait and balance training This group will receive 6 weeks of balance training, 3 sessions per week. Each session will take 40-60 minutes and each exercise will repeat 5-8 times. Each exercise takes 30 seconds, with a 15-second rest between exercises.
Category
Rehabilitation

2

Description
Intervention group 2: dual-task gait and balance training This group will receive 6 weeks of balance training concomitant with a cognitive task (including naming, remembering and backward counting) , 3 sessions per week. Each session will take 40-60 minutes and each exercise will repeat 5-8 times. Each exercise takes 30 seconds, with a 15-second rest between exercises.
Category
Rehabilitation

3

Description
Control group: without intervention This group will receive no intervention during the 6-week period of the trial.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Jahandidegan Center
Full name of responsible person
Roya Razavi
Street address
Kholdebarin Park, Beesat St., Shiraz
City
Shiraz
Province
Fars
Postal code
Phone
+98 71 3647 5010
Email
razaviroya41@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3336 2414
Email
Badavi-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation Sciences; Madadkaran Aly; Shahnazari Av.; Madar Sq.; Tehran
City
Tehran
Province
Tehran
Postal code
۱۳۴۸۷ - ۱۵۴۵۹
Phone
+98 21 2222 7124
Email
salehi200@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences; Madadkaran Aly; Shahnazari Av.; Madar Sq.; Tehran
City
Tehran
Province
Tehran
Postal code
1348715459
Phone
+98 21 2222 7124
Email
salehi200@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences; Madadkaran Aly; Shahnazari Av.; Madar Sq.; Tehran
City
Tehran
Province
Tehran
Postal code
1348715459
Phone
+98 21 2222 7124
Email
salehi200@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The data of the participant alone is useless.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results of primary outcomes will be shared.
When the data will become available and for how long
two months after the publication of the results.
To whom data/document is available
academic researchers
Under which criteria data/document could be used
Once accessed, individuals have the right to use the study protocol for rehabilitation purposes.
From where data/document is obtainable
Samira Javadpour will be responsive through email. samira.javadpour@yahoo.com
What processes are involved for a request to access data/document
After receiving the request and mentioning the reasons for the request, the data will be answered within a maximum of one month.
Comments